Remarks

A Request for Continued Prosecution has been filed. Claims 4, 5, 8-12, 26, 27, 30, and 32 have been withdrawn as directed to a non-elected invention. In accordance with M.P.E.P. § 809 and as noted in the Office Action dated October 4, 2004, these claims will be examined upon the allowance of the linking claims, i.e. claims 1, 2, 14-28, and 31. Therefore, the withdrawn claims are still pending and amended, as appropriate.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 1, 3, 6, 7, 13-25, 28, 29, 31, and 33-37 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement and as indefinite. These rejections are respectfully traversed.

The limitation and agents in a form suitable for local delivery, as listed, is described at page 7 and in the original claim 5.

Use of the polymer as a carrier is described at page 12, lines 12-13, and page 13, lines 2-4. See also page 14, lines 26-28, page 15, lines 26-30, page 16, lines1-3, page 22, lines 9-22; page 23, lines 6-17; page 27, lines 15-22.

Accordingly, the previous amendments do not represent new matter.

Claims 1 and 15 have been amended to specifically recite polymer coatings as means for delivery. Support is found as noted above for use of the polymer as carrier.

Claims 15 and 25 have been amended to incorporate the limitation of claim 23.

Claims 1, 15, and 15 have been amended to define the means for penetration as cutting or removing tissue. Support is found at page 11, lines 23-27 to page 12, line 2; original claims 15, 19, and 25. The specification describes a number of penetrating and cutting means that are designed to cause minimal collateral damage to tissue surrounding the site where a void is created (*see e.g.* page 9, lines 1-19; and Figures 3-5). Support for this amendment can be found in the specification at least at page 7, lines 10-15 and page 11, line 10.

Claims 1 and 15 have been amended to make it clearer that one creates a space into which the material is deposited. This can occur simultaneous, or sequentially (claim 14).

Claim 35 has been amended to correct antecedent basis.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 1-3, 6, 7, and 13-15 were rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. Applicants respectfully traverse this rejection.

The undersigned respectfully requests an interview if this rejection is maintained. It is a highly unusual rejection in a mechanical field when the invention is not the selection of treatment of some specific disorder, but a method of and means for delivery of therapeutics and other materials having known properties. Applicants has many issued patents on treatment of disorders by application of polymeric materials and drugs to the endoluminal surface of various organs and tissues. Many products are currently on the market for such applications (such as the drug eluting stents for preventing restenosis). The difference here is that the materials are applied endoluminally, using a device which creates a void, and which has means for direct or

indirect guidance.

The specification is presumed to be enabled. It is well established that the examiner must provide more than mere allegations that something is not enabled. In this case, as discussed below, the examiner has acknowledged that applicant has provided examples – actual working examples, even though none are required. Applicant has provided extensive discussions of means and materials that can be used. The amended claims define a method for treating an organ, organ component, or tissue structure by delivering a therapeutic agent or system to the endomural zone of the organ, organ component, or tissue structure and devices and kits for practicing this method. The state of the art is well-established. Surgical methods, percutaneous administration and similar procedures have been practiced for many years. The endomural zone is well-defined in the specification and well-known in the art (see e.g. page 6, lines 1-28), as acknowledged by the examiner. The specification provides many examples of organs, organ components, and tissues to be treated (see e.g. page 4, lines 21-26, regarding the myocardium of the heart; page 5, lines 19-26, listing organs and organ components; and page 6, lines 1-30, discussing the location of the endomural zone), and suitable methods and devices with which to treat the endomural zones of these organs, organ components, and tissues (see e.g. page 9, line 1 until page10, line 19 and Figures 3-5).

It is not sufficient in a case of this type to merely allege that this is insufficient. The presumption is that the specification is enabled. The examiner must rebut this presumption. Should the examiner do so, then applicant may provide additional evidence or argument as to

enablement. However, allegations are not sufficient to rebut the presumption.

The Court of Appeals for the Federal Circuit (CAFC) has described the legal standard for enablement under § 112, first paragraph, as whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art, without undue experimentation (*See, e.g., Amgen v. Hoechst Marion Roussell,* 314 F.3d 1313 (Fed. Cir. 2003; *Genentech, Inc. v. Novo Nordisk A/S*, 108 F3d at 165, 42 USPQ2d at 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation (*M.I.T. v. A.B. Fortia*, 774 F.2d 1104 (Fed. Cir. 1985)).

Whether the disclosure is enabling is a legal conclusion based upon several underlying factual inquiries. See *In re Wands*, 858 F.2d 731, 735, 736-737, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir.1988). As set forth in *Wands*, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly

extensive." *Atlas Powder Co., v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir.1984). There is no requirement for examples.

The level of skill in this field is very high. One of ordinary skill in the art would know how to make and use the claimed method and device without undue experimentation.

Rejection Under 35 U.S.C. § 102

Claims 1-3, 6, 7, 15-18, 20-23, 25, 28, 29 and 35-37 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,585,716 to Altman ("Altman '716"). Claims 1, 3, 6, 7, 15-18, 19, 21-23, 25, 34, 36 and 37 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,102,887 to Altman ("Altman '887"). Claims 1, 3, 6, 7, 14-16, 18, 20-24, and 34-37 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,309,370 to Haim *et al.* ("Haim"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Altman '716

Altman '716 describes methods for treating the human heart. A guide catheter is placed in the venous portion of a patient's vasculature and extends until the vena cava and coronary sinus. A drug delivery catheter is inserted inside the guide catheter and extends beyond the guide catheter so that the tip enters the cardiac vein and extends to the posterior vein. The tip contains a penetrating element, such as a curved or helical needle, that is selectively extended into the wall of the vein and into the myocardium. Therapeutic agents are injected into the myocardium, through the needle (col. 4, lines 5-19 and Figure 1). The guide catheter contains an

occluding mechanism. The venous flow path is shut off by occluding the oronary ostium with the occluding mechanism. This stops the natural blood flow from the myocardium into the vein, thereby preventing the therapeutic agents from being flushed out of the myocardium in the course of normal blood flow. (col. 4, lines 20-47)

Altman does not disclose cutting or removal of tissue. Altman does not disclose the use of direct or indirect guidance means. Therefore, Altman does not disclose the method or device as defined by the amended claims.

Altman '887

Altman '887 describes a steerable catheter with a deployable penetrating element, such as a helical or straight needle, for administration of drugs to the heart (col. 3, lines 9-22). Col. 9, lines 20-52 discloses an expanding prong fixation system, which may be used to *stabilize* the needle, *not* to create a void. Altman does not disclose including direct or indirect guidance means. Therefore, Altman '877 does not disclose every step of the claimed method or device.

Haim

Haim discloses a method and device for delivery of growth factors to an ischemic region in the heart. Haim emphasizes the importance of navigating the catheter to the site of the ischemic regions (see col. 4, lines 25-40). The device is a catheter that contains sensors to determine the position of the catheter with respect to the heart wall (col. 12, lines 10-28). When the device is in place, the needle is placed inside the heart wall and the growth factors are delivered (see e.g. col. 12, lines 40-49 and col. 13, lines 39-50 and col. 14, lines 3-11). The

growth factors may be administered in a solution or a capsule (see col. 15, lines 14-20). . Haim does not disclose administering agents in a carrier such as porous matrices, hydrogels, organogels, colloidal suspensions, microparticles, microcapsules, or nanoparticles. Therefore claim 1 and its dependent claims, claims 3, 6, 7, 14, and 34-37are novel over Haim.

Haim does not disclose means for creating a void. Haim merely penetrates the heart wall and administers a therapeutic using a needle. Therefore claim15, and its dependent claims, claims 16-18 and 20-23, are novel over Altman '877.

Rejection Under 35 U.S.C. § 103

Claims 13 and 33 were rejected under 35 U.S.C. § 103(a) as being obvious over Altman '716, Altman '887, or Haim, in view of Benjamin & McMillan, *Circ. Res.*, 83: 117-132 (1998) ("Benjamin"). Claim 31 was rejected under 35 U.S.C. § 103(a) as being obvious over Brösamle, et al., *J. Neuroscience*, 20(21):8061-8068 (2000) ("Brösamle"), in view of Altman '716, Altman '887, or Haim. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Claims 13 and 33

Claim 13 is a method claim that depends from claim 3 and further defines the therapeutic agent as a heat shock proteins, stress response proteins, or inducers of heat shock or stress response proteins. Claim 33 is a kit claim that depends from claim 25 and further defines the kit as containing stress response inducing agents or stress response proteins.

The combination of Altman '716, Altman '887, or Haim with Benjamin

As noted above, Altman '716 does not disclose the local administration of therapeutic agents or systems. Altman '887 does not disclose the local administration of therapeutic agents or systems. Haim does not disclose local administration of an agent in a carrier, such as porous matrices, hydrogels, organogels, colloidal suspensions, microparticles or microcapsules, or nanoparticles. Additionally Haim does not disclose including a void filling material or implant in the device. None of Altman and Haim disclose creating a void by cutting or removing tissue. Neither Altman discloses indirect or direct guidance means.

Benjamin is a general reference about heat shock proteins and some of their roles. Benjamin does not cure the deficiencies of Altman '716, Altman '887, and Haim. The combination of these references still does not disclose or suggest delivering heat shock proteins, stress response proteins, and inducers of heat shock or stress response proteins in a form suitable for local administration as defined by claim 13. Additionally, the combination of Benjamin with Altman '716, Altman '887, and Haim does not disclose a kit containing a void filling material or implant is in a form suitable for local administration, as required by claim 33.

Claim 31

Claim 31 is device claim that depends from claim 15 and further defines the device as being suitable for nerve regeneration.

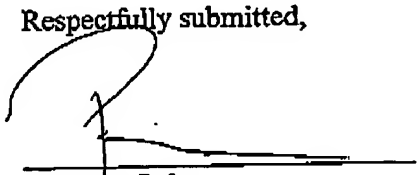
The combination of Brösamle with Altman '716, Altman '887, or Haim

As noted above, Altman '716, Altman '887 and Haim are limited to devices that use needles to penetrate a tissue and administer a therapeutic agent. None of these references

disclose a device that is able to create a void by cutting or removal of tissue. Brösamle describes administering an antibody to the spinal cord to promote regeneration. Brösamle does not cure the deficiencies Altman '716, Altman '887 and Haim. Brösamle does not disclose a device with means for means for creating a void. Therefore the combination of Brösamle with Altman '716, Altman '887, or Haim does not make claim 31 obvious.

Allowance of claims 1, 3, 4, and 6- 37, as amended, is respectfully solicited.

Respectfully submitted,



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